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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,834	06/26/2000	Michael Kraus	39727/DBP/E43	2410
23363	7590 09/10/2003			
CHRISTIE, PARKER & HALE, LLP 350 WEST COLORADO BOULEVARD SUITE 500			EXAMINER	
			OROPEZA, FRANCES P	
PASADENA,	CA 91105		ART UNIT PAPER NUMBER	
			3762	0
			DATE MAILED: 09/10/2003	$\mathcal{V}$

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)	•
	09/603,834	KRAUS ET AL.	
Office Action Summary	Examiner	Art Unit	
	Frances P. Oropeza	3762	_
The MAILING DATE of this community Period for Reply	nication appears on the cover sheet wit	h the correspondence address	
A SHORTENED STATUTORY PERIOD R THE MAILING DATE OF THIS COMMUN  - Extensions of time may be available under the provision after SIX (6) MONTHS from the mailing date of this com  - If the period for reply specified above is less than thirty ( - If NO period for reply is specified above, the maximum s - Faiture to reply within the set or extended period for repl - Any reply received by the Office later than three months earned patent term adjustment. See 37 CFR 1.704(b).  Status	SICATION.  Is of 37 CFR 1.136(a). In no event, however, may a remunication.  30) days, a reply within the statutory minimum of thirty statutory period will apply and will expire SIX (6) MONT will, by statute, cause the application to become AB/	ply be timely filed  (30) days will be considered timely.  HS from the mailing date of this communicatio  NDONED (35 U.S.C. § 133).	n.
_	iled on <u>7/7/03 (Amendment) and 8/11/</u>	(03 (RCF)	
2a) ☐ This action is FINAL.	2b)⊠ This action is non-final.	<u>00 (NOL)</u> .	
3) Since this application is in condition	on for allowance except for formal matter ctice under Ex parte Quayle, 1935 C.D		is
Disposition of Claims	stoc ander Expante Quayle, 1999 C.L	. 11, 400 0.0. 210.	
4)⊠ Claim(s) <u>2-5, 7 and 9-23</u> is/are per	nding in the application.		
4a) Of the above claim(s) is/s	are withdrawn from consideration.		
5) Claim(s) is/are allowed.			
6)⊠ Claim(s) <u>2-5, 7 and 9-23</u> is/are reje	cted.		
7) Claim(s) is/are objected to.			
8) Claim(s) are subject to restri	ction and/or election requirement.		
Application Papers			
9) The specification is objected to by the specific of the	ne Examiner.		
10)☐ The drawing(s) filed on is/are	: a)☐ accepted or b)☐ objected to by th	e Examiner.	
	ojection to the drawing(s) be held in abeya	·	
11) ☐ The proposed drawing correction file		sapproved by the Examiner.	
If approved, corrected drawings are re	,		
12) ☐ The oath or declaration is objected t	o by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120			
13) Acknowledgment is made of a clair	n for foreign priority under 35 U.S.C. §	119(a)-(d) or (f).	
a) ☐ All b) ☐ Some * c) ☐ None of:			
<ol> <li>Certified copies of the priority</li> </ol>	documents have been received.		
2. Certified copies of the priority	y documents have been received in Ap	plication No	
	s of the priority documents have been in the priority documents have been in the certified copies not record for a list of the certified not record for a list of the list of the certified not record for a list of the certified not record for a list of the list of t	•	
14) Acknowledgment is made of a claim	for domestic priority under 35 U.S.C. §	119(e) (to a provisional applicat	ion).
a) ☐ The translation of the foreign la 15)☐ Acknowledgment is made of a claim	nguage provisional application has be for domestic priority under 35 U.S.C.		
Attachment(s)			
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review ( 3) Information Disclosure Statement(s) (PTO-1449)	PTO-948) 5) Notice of Ir	ummary (PTO-413) Paper No(s)  Iformal Patent Application (PTO-152)	
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#### DETAILED ACTION

### Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 8/11/03 has been entered.

## Claim Rejections - 35 USC § 112

2. Claims 2-5, 7 and 9-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Independent claims 21 and 23 include the limitation of "the first transmitter/receiver unit beginning data transmission by sending a triggering signal to the second transmitter/receiver unit repetitively at the end of a first pre-determined time interval". The Applicant notes in his Remarks/ Arguments filed 7/7/03 that support for the amendment can be found on pages 24-30 of the specification and continues that the amended/ new claims are described in the specification ... such that the invention is particularly pointed out and distinctly claimed. The Examiner notes that while the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Claims 2-5, 7 and 9-23 are indefinite because it is not clear what is done repetitively and what enables the invention to move from repetitively doing something to proceeding with the other portions of the data transmission process. Claims 21 and 23 are read such that the first

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transmitter sends the triggering signal repeatedly after the end of the first time period, but it is not clear when the first transmitter stops sending the triggering signal. In reading the sections of the specification referenced by the Applicant, it appears the triggering signal is repeated by the first transmitter/ receiver unit only if the data is invalid (specification – page 25, lines 3-5, page 26, lines 1-3). If the data is invalid and the number of renewed transmission attempts exceed a predetermined number, the data is not repeated even if it is invalid (specification – page 24, line 27 – page 25, line 2). Clarification is needed and appropriate correction is required.

3. The remaining limitations of claims 2-5, 7 and 9-23 appear to be previously examined limitations, hence a clear understand of "repetitively" is essential for continued examination.

Based on a lack of understanding by the Examiner, the rejection shown below generally reflects the rejection of record.

As to the Applicant's argument regarding a first item of control information, the synchronization code is read as the first item of control information; the control information relating to the serial number of the implant (col. 17 @ 20 - 47).

As to de Coriolis, the Examiner is unable to follow the Applicant argument related to renewed transmission of data as a specific claim was not identified with the arguments.

# Claim Rejections - 35 USC § 103

4. Claims 2-4, 7, 9-17 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al. (US 5113869) in view of de Coriolis (EPO 0607638).

Nappholz et al. disclose an implantable ambulatory monitor. The telemetry receiver/transmitter performs two-way, digital telemetry to transfer data and programs between

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triggers communication with an external device using a beacon signal indicating the reception readiness of the implant, and uses two intervals to control the receiving portion of the implant receiver/transmitter (col. 16 @ 61 – col. 17 @ 6). The reception readiness of the implant is controlled by the synchronization sequence, read as "at least one first item", sent by the external device (col. 17 @ 13-47). The external receiver/transmitter is substantially permanently ready for data exchange (col. 17 @ 22-25). The implant initiates communications with an external device to provide a warning about abnormal conditions or about implant malfunction (col. 16 @ 34-44). Data communications can be initiated by the implant (col. 21 @ 31-43).

As discussed in the previous paragraph of this action, Nappholz et al. disclose the claimed invention except for:

- the triggering signal including a first data set (claim 4),
- implementing a first plausibility check (claim 21 and 23),
- implementing renewed transmissions if the power supply is not exceeded (claim 9),
- checking the data (claim 10),
- sending a second acknowledgement (claim 11),
- implementing a second plausibility check (claim 12),
- effecting a new transmission when a defective transmission is established (claim 13),
- effecting renewed transmission after expiry of a waiting time period (claim 14),
- after renewal of the transmission, repeating the method steps (claim 15), and
- upon non-reception of transmissions, prolonging the transmission (claim 17).

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De Corlolis discloses a telemetry system for an implantable device including an implant device receiver (44) and transmitter (46) and an external programmer receiver (32) and transmitter (34). The telemetry circuit is used intermittently and contains a wakeup command transaction to enable full activation of the telemetry means (28) (col. 10 @ 49-59). During periods of quiescence, the telemetry means, at spaced apart time intervals, enters a partially active state to detect energy transmissions. If energy is detected, further detection occurs seeking the transmitted initiation command. Once the initiation command is detected, the telemetry system becomes fully active, the receiver sends a response code and the communication transaction begins (col. 11 @ 1-22; col. 20 @ 14-26). The outbound data packet is grouped in fixed length frames, read as intervals, with a preamble (58), a data field (62), a control byte (64), a frame check (containing error code to trigger resending of the data, read as a first acknowledgment) and a postamble (68) used for error detection (col. 12 @ 9-33). The inbound data packet contains a leading flag (74), a data field (78), a control byte (76), a frame check (80) (containing error code to trigger resending of the data, read as a second acknowledgment) and a trailing flag (82) (col. 14 @ 2-12). The preamble (58) and the leading flag (74) are read as the triggering signals; this frame contains a first data set and second data set respectively in the data fields. The stay awake signal is read as the waiting time interval (col. 21 @ 37-41). In is inherently understood transmission would not take place in a low battery scenario as therapeutic operations of the implant take priority. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable ambulatory monitor as taught by Nappholz et al., with the specifics of the signal modulation and system component interaction to enable signal transmission as taught by de Coriolis so a known and

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proven means of signal modulation and system component interaction is adopted to enable data transfer between the implanted device and the remote external unit so the patient's condition can be evaluate the patient's care optimized.

5. Claim 5 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Nappholz et al. (US 5113869) in view of in view of de Coriolis (EPO 0607638) and further in view of Fountain et al. (US 4625730). As discussed in paragraph 4 of this action, modified Nappholz et al. disclose the claimed invention except for the triggering signal being initiated by the wearer.

Fountain et al. disclose an ECG recording controller and teach that it is known to provide a manual means for initiating a triggering pulse to begin a transmission when the patient perceives an emergency situation (abstract; col. 6 starting @ 23). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable ambulatory monitor as taught by modified Nappholz et al., with the manually initiated emergency signal as taught by Fountain et al. to provide a system with a means that enables the patient to get help when he perceives help is needed.

6. Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over
Nappholz et al. (US 5113869) in view of in view of de Coriolis (EPO 0607638) and further in
view of Wyborny et al. (US 5354319). As discussed in paragraph 4 of this action, modified
Nappholz et al. disclose the claimed invention except for the intervals varying in length.

Wyborney et al. disclose a telemetry system and teach that it is known to use variable interval lengths (col. 5 @ 53-58). Therefore it would have been obvious to one having ordinary

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skill in the art at the time the invention was made to modify the implantable ambulatory monitor as taught by modified Nappholz et al., with the variable interval lengths as taught by Wybroney et al. to compress the frame length so more data can be transmitted in a fixed time.

# Claim Objection

7. Claim 23 is objected to because in line 7 it appears "repetivevly" should be --repetitively--.

### Statutory Basis

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza Patent Examiner

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ANGELA D. SYKES SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700